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Results of endovenous ClosureFast treatment for varicose veins in an outpatient setting

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Short title: Radiofrequency ablation for varicose veins in outpatients

Key words: varicose veins, radiofrequency, endovenous laser (EVLT)

Abstract

Objectives: Endovenous methods are increasingly used to treat varicose veins. We evaluated the outcome of patients treated with the new RFA-ClosureFast catheter in an outpatient setting.

Methods: Retrospective analysis of postinterventional duplex ultrasound (DUS), complication rate and quality of life of patients treated for incompetent saphenous veins.

Results: Between 2007 and 2009 155 patients had been treated with ClosureFast. DUS was available from 73 (47%) patients (102 great (GSV) and 16 small (SSV) saphenous veins). After a mean follow-up of 12.2 months (range 1-29 months) DUS showed six (5.9%) open GSV and an occlusion of all treated SSV. One pulmonary embolism had occurred. Mean patient's satisfaction was 8.7 (10=very satisfied), pain after one week 2.0 (no pain=0, maximal=10) and absence of work was 0.9 day (range 0-14 days).

Conclusions: RFA for incompetent saphenous veins can safely be performed in an outpatient setting with a low complication rate, minimal pain and fast recovery.

Introduction

The popularity of endovenous treatment for varicose veins has steadily increased over the past years. It allows to be treated as an outpatient and the return to work is quicker¹⁻⁵. At the present time large patient studies and long-term follow-up of randomized trials comparing surgical methods with endovascular treatment modalities for varicose veins are not available. Darwood et al. published the results of 42 surgically treated legs compared with 29 legs treated with endovenous laser ablation (EVLA) and found comparable results regarding abolition of reflux and quality of life after three months². Studies comparing different catheter-directed techniques have been published; however many of them are retrospective studies⁶⁻⁸. In 2008, Luebke and Brunkwall published a meta-analysis including studies from 1970 to 2007 of endovenous radiofrequency ablation (RFA), EVLA and foam sclerotherapy for primary varicosis⁹. They concluded that all these techniques *“seem to be safe and effective modalities with good short and mid-term results”*. However, RFA had the least favorable outcome and they suggested that a prospective, randomized study comparing surgery with endovascular techniques is needed.

Van den Bos et al. could demonstrate quite clearly a superiority of laser light over radiofrequency (VNUS Closure)¹⁰. The original VNUS Closure technique can also be considered inferior to laser in terms of ease of handling. However, the original radiofrequency technique was replaced by the ClosureFast technique in 2007. The catheter embodies a heating coil with a length of 7cm at its tip heating the venous wall predictably to about 110 degrees Celsius during 20 seconds. Thereafter, the catheter is pulled to the following segment and the next cycle begins.

Proebstle et al. reported their initial experience with the new ClosureFast in 2008 in a prospective multicenter study involving 194 patients (252 GSV) with an average diameter of the treated vein of 5.7 mm and an occlusion rate of 99.6% at six months¹¹.

The aim of the present retrospective analysis was to evaluate patient satisfaction, the recurrence of saphenous reflux, complications and periprocedural pain after ClosureFast treatment in an outpatient setting.

Under Review

Patients and Methods

Patients treated from 2007 to 2009 for incompetent saphenous veins with ClosureFast radiofrequency ablation had been included in the analysis. All patients had symptoms or cosmetic disturbances from varicose veins. On ultrasound, reflux of more than one second was present in at least one saphenous vein. According to the CEAP classification, 70 patients (45%) were classified C2 (visible varicosities), 60 patients (39%) C3 (oedema) and 23 patients (15%) C4 (skin changes). Two patients had healed ulcers. Among all interventions performed for the treatment of varicose veins at the institution, the use of ClosureFast was 33% in 2007, 48% in 2008 and 64% in 2009. The reasons for stripping were a very superficial or very tortuous course of the varicose saphenous vein. However, the reimbursement question was crucial. In Switzerland, the majority of the numerous insurance companies do not reimburse endovascular methods. Therefore a considerable share of our patients decided to have an operation rather than paying the treatment by themselves.

The catheter-based endovascular intervention with ClosureFast (Medical Technologies Inc., San Jose, California) has been described elsewhere¹². In brief, depending on the extent of the insufficiency the puncture site of the vein can be above or below the knee or near the ankle. A 7-F catheter sheath is placed into the vein and the ClosureFast catheter advanced to the groin or to the popliteal fossa. The ClosureFast ablates the vein in 7cm segments with 20-second treatment cycles at a temperature of 120 degrees Celsius and is withdrawn stepwise. The therapy is performed under tumescent local anaesthesia. The solution consisting of one litre of normal saline, 50ml Lidocain 1%, 1mg of adrenalin and 10ml potassium bicarbonate 8.4% is injected under ultrasound guidance around the refluxing vein with the catheter "in situ", and around visible varicosities marked previously with a permanent marker in an upright position. The visible varicosities are treated by phlebectomy in the same session.

After the procedure, absorbing gauzes and thigh compression stockings (20-30mmHg) were applied. Patients were discharged after the procedure and allowed to take off the bandages

the day after. Stockings were prescribed for one week. In order to reduce the thromboembolic risk patients were encouraged to avoid a sedentary lifestyle, but no anticoagulation was prescribed. All patients were asked to fill in two identical questionnaires in order to assess their quality of life score (CIVIQ2 questionnaire)¹³. The first questionnaire assessed baseline condition prior to the intervention, the second focused on postinterventional outcome. The scale for the variables was from one (no complaints/pain) to five (most intensive complaints/pain). Additionally, patients had been specifically asked to indicate on the questionnaire the days off work, the level of pain during and one week after the procedure, as well as satisfaction with treatment and with the result on a scale from zero (no pain/satisfaction) to ten (maximal pain/satisfaction). The questionnaires were sent by mail to the patients before the follow-up visit. Patients had been contacted by the operator if they were willing to come to the university hospital Zurich for an independent quality control including the questionnaires and a duplex ultrasound.

Duplex ultrasound (DUS) was performed between one and 29 months after the procedure depending on patient's availability to assess occlusion of the GSV defined as absence of flow 20cm below the saphenous femoral junction (SFJ) and non-compressibility. Flow was also measured at 1 and 3cm and the vein diameter at 3 and 20cm distal to the SFJ. Furthermore, flow and compressibility of the femoral and popliteal vein as well as calf veins were tested in order to detect deep venous thrombosis. In SSV successful occlusion was defined as no flow over the treated length of the vein and non-compressibility. In veins with flow the presence of reflux was tested by distal decompression and proximal compression and in GSV also with Valsalva maneuver.

Statistics

All statistical analyses were made with the SPSS 17 for Windows using Wilcoxon signed rank test for intragroup and Mann-Whitney U test for intergroup comparison. A p value of less than 0.05 was considered significant.

Results

From 2007 to 2009 190 GSV and 42 SSV of 155 (111 female) patients were treated with the ClosureFast technique. In all patients the GSV and/or SSV were successfully accessed percutaneously via ultrasound-guided puncture. The puncture site was above the knee in 29 (12.5%), below the knee in 139 (60%) and near the ankle in 64 (27.5%) cases. On average six segments (range 2-10) of the GSV were treated and three (1-5) segments of the SSV. The mean treatment length was 45cm (range 13-75cm) for the GSV and 23cm (range 7-35cm) for the SSV. The proximal segments of the GSV were treated with two cycles if the vein had a diameter of more than 8mm. All refluxing saphenous veins were treated and all varicose branches removed by hook phlebectomy in the same session.

CIVIQ2 questionnaire

Ninety-four (60.6%) patients had returned the questionnaires. The results of the questionnaires are given in table 1 and 2. In all patients quality of life score improved after the procedure. The mean value for pain during the procedure was 3.1 (range 0-10) and for pain one week after the intervention 2.0 (range 0-10). Pain was independent from the treated vein and was similar in patients treated bilaterally or unilaterally ($p>0.05$). Patients went back to work after a mean time of 0.9 days (range 0-14 days). Seventy-six (82%) patients had no inability to work at all. The overall satisfaction with the treatment was 8.7 (range 1-10) and satisfaction with the final result was 8.0 (range 1-10) on a scale from zero (not at all) to ten (fully satisfied) and there was no difference in patients treated for GSV or SVV, bilaterally or unilaterally.

Duplex Ultrasound

Data of DUS were available from 73 (47%) patients in which 118 saphenous veins had been treated (102 GSV, 16 SSV). The residual 82 patients were not willing to come for a control DUS. The mean follow-up time was 12.2 months (range 1-29 months). Baseline statistics are given in table 3. The mean age of the patients was 54 years (range 19-89 years). Six (5.9%) of the 102 treated GSV (four patients) were open defined as flow in the treated GSV 20cm below the SFJ. None of the open GSV showed reflux 20cm below the SFJ. Flow was detected in 78 (76.5%) veins at 1cm and in 13 (12.7%) veins at 3cm below SFJ. No flow signal was detected in any of the treated SSV (table 4).

For the GSV the mean diameter was 0.3cm (range 0-1.0cm) at 3cm and 0.2cm (range 0-0.8cm) at 20cm below the SFJ. In SSV mean diameter was 0.2cm (range 0-0.7cm) at 3cm and 0.1cm (range 0-0.6cm) at 20cm below the SFJ. The diameter of the GSV decreased with time and was significantly correlated with the follow-up time ($p<0.0001$).

Four patients with open GSV suffered significantly more pain during the first week (mean 4.75, range 3-8 versus mean 1.90, range 0-10; $p=0.001$) compared to those with occluded veins. Furthermore, the diameter was significantly larger at 3cm (mean 0.65cm, range 0.32-0.9cm) and at 20cm (mean 0.38cm, range 0.2-0.59cm; $p=0.007$) below SFJ in open compared to occluded veins. Despite the open vein no reflux was present. Follow-up time, age and BMI did not influence the result of DUS.

Adverse events

The adverse events are summarized in table 5. Ten (13.7%) patients (4.2% of treated veins) reported paresthesia which was not specifically verified by an objective method. Four (5.5%) patients developed hyperpigmentation. In one patient a thrombophlebitis occurred at the puncture site and one patient suffered from a pulmonary embolism two weeks after the intervention. This patient was later diagnosed with a thrombophilia. No deep venous thrombosis was detected by DUS. No residual varicose veins were detectable. All patients

were satisfied with the outcome. No patients with leg ulcers had been treated. During follow-up no leg ulcers had developed.

Under Review

Discussion

ClosureFast catheter

Based on the published data there is sufficient evidence that catheter-directed heat application can be considered a safe procedure with good long-term results for the treatment of incompetent saphenous veins¹⁴⁻¹⁷. We evaluated the results of RFA in an outpatient setting and focused on patient satisfaction and results from follow-up duplex ultrasound. The occlusion rate of 94.1% after one year in the present study is better than reported in other studies analyzing RFA with the older Closure catheter⁶. However, Proebstle et al. had reported a higher occlusion rate (99.6%) after 6 months with the same catheter¹¹. This might be explained by the fact that in our cohort the mean follow-up time was longer and therefore more recanalisation may have occurred. Still, even if some flow was detected in the treated vein, the diameter was small and no visible varicose veins had been present and no reflux was detected. Comparing our results with published data from EVLA the occlusion rate after one year is similar³⁻⁴.

Adverse events

It is difficult to compare the rate of side effects with other thermoablative methods because different energies are used. Furthermore, in most studies the new ClosureFAST catheter was tested against older EVLA-systems with lower wavelengths and no radial LASER-fiber. Interestingly, there are no data about side effects comparing the two RFA systems, the segmental RFA (ClosureFAST) and the bipolar RFA (Celon RFiTT). To our knowledge there is only one study comparing the old bipolar ClosurePLUS with the new segmental RFA (ClosureFAST), but side effects of the bipolar system are not mentioned¹⁸.

The incidence of postinterventional phlebitis is lower in our patient group (1.4%) than it was reported for EVLT (2-6%)¹⁹⁻²⁰. Paresthesia was found in 4.2% of treated veins and was independent of follow-up time. Slightly lower rates of paresthesia are published for EVLA (0-2.34%) but also for RFA, thus it is unclear how the diagnosis of paresthesia was made^{18, 21-22}.

The rather high rate of paresthesia in our cohort might be due to the fact that patients were asked by questionnaire about any type of paresthesia without specific explanation about the type of disturbance or exact location. Other side effects were similar in our patient group compared to published results of either EVLA or RFA. One patient (1.4%) developed a non-fatal pulmonary embolism, but no deep venous thrombosis was detected. The reported incidence of deep venous thrombosis is low (0.3-7.7%) and not different in EVLA and RFA and so far pulmonary embolism has been reported only in single cases^{6,23-24}. Selective adjunctive saphenous vein ligation has not proven a benefit regarding pulmonary embolism or long-time result²⁵.

Questionnaire

Quality of life was analyzed using two questionnaires which were sent to the patient by mail (table 1). Pain and any limitations due to leg problems improved significantly after the intervention. Patients with varicose veins felt often tired due to leg problems and significant improvement was noted after the treatment. In addition, significant improvement of social function, sporting activities and housework was noted after therapy. These results show clearly how varicose veins influence daily activities and how treatment has a positive effect on important aspects of life. Patients with varicose veins feel often embarrassed which influences their social life. From our data we can conclude that quality of life in many different aspects improved after therapy which may lead to a healthier lifestyle (for example increased sporting activities after treatment).

Costs

Subramonia et al. showed that RFA is more expensive than conventional surgery²⁶. In their study both treatments were performed in the operating room. The main difference in costs was due to the RFA catheter and the longer use of the operating room. Even the fact that RFA patients gained one working week did not compensate for these additional costs. All our

patients had been treated in an examination room and faster ablation was possible due to the new ClosureFast catheter.

Learning curve

One of the technical difficulties in heat ablation for varicose veins is ultrasound guided puncture. The main operator of the present series (ME) had limited experience in endovenous laser ablation before starting with the ClosureFast method. In the present series, all 155 ClosureFast procedures were carried out in cooperation with a very experienced physician (more than 1000 ultrasound guided punctures for EVLT or RFA). Well-aimed and sufficient injection of tumescent local anaesthesia solution undoubtedly takes time to learn. At the beginning of the series more patient experienced pain and required interruption of the heating process and additional local anaesthesia than at a later stage.

However, serious problems might occur when thermoablation is erroneously applied to proximal to the common femoral vein. We found it difficult on a few occasions in obese patients to exactly localise the tip of the catheter. In such a situation it is important to estimate the needed length of the catheter before it is introduced and the ultrasound probe needs to be perfectly parallel to the catheter in order to correctly localise the tip.

Future

A wide range of methods to produce and deliver heat have been presented in only one decade and there is no doubt that further techniques will evolve. With RFA technique repeated treatment of the saphenous vein during the same intervention might be necessary whereas with EVLA the pullback treatment time is shorter. Independent of the method it is crucial to carefully assess the venous anatomy prior to the intervention by DUS to localize incompetent branches, which may be treated at the same time by other means.

Comparison of results is difficult due to different inclusion criteria regarding CEAP classification as well as different thermal energies, follow-up methods and periods and also operator experience. Therefore, it is desirable to develop a set of guidelines for clinical trials

evaluating endovenous ablative methods to ensure a consistent approach in design and reporting of data.

Conclusion

For several reasons including patients preference and health costs there is certainly a shift towards shorter hospitalization stay and outpatient treatments. Based on our data ClosureFast can be performed in an outpatient setting with a very high level of patient satisfaction, low postprocedural pain, low complication rate and almost immediate return to work.

Under Review

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